Kentucky Lung Cancer Research Program

2010 Strategic Plan Update

Approved by the KLCR Program Governance Board
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KLCR Program Strategic Plan

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Kentucky Lung Cancer Research Program (KLCR Program)

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Introduction

In 2000, the Kentucky General Assembly passed enabling legislation that created the Lung Cancer Research Fund, a partnership of the Cancer Centers at the University of Kentucky and University of Louisville under the leadership of a Governance Board of the Lung Cancer Research Fund. This legislation required development of research expertise in lung cancer at each Cancer Center, innovative clinical trials to test new lung cancer treatments throughout the Commonwealth, and leveraging this support to lead the centers toward designation as National Cancer Institute recognized Cancer Centers.

The enabling legislation focuses on lung cancer research and complements the mission of the Commonwealth's two medical research universities in helping Kentuckians gain or retain their good health. To accomplish this mission, each university strives to meet the educational, research, and patient care needs of our citizens working cooperatively together as well as with similarly focused organizations throughout the Commonwealth.

The Governance Board set initial strategies and goals for the Program. The following Strategic Plan Update for 2010 delineates specific goals, objectives, strategies and measurable outcomes and provides a blueprint for the two universities to follow as they continue to build the nation's centerpiece of lung cancer research in Kentucky.

GOAL 1: Investigator-Initiated Research

"167.476(5)(a) Develop an expertise in the area of lung cancer research"

The conduct of investigator-initiated, hypothesis-driven research – i.e., independently conceived research approaches and projects developed by scientists from all relevant disciplines - is the primary means by which biomedical research is advanced. Driven by state of the art knowledge and creative synergism present at medical schools, hospitals, universities, research centers, and corporations they represent, these highly trained investigators:

- Review current scientific knowledge and identify critical gaps
- Develop new hypotheses
- Design the most direct pathways to test those hypotheses
- Utilize and develop novel molecular, genetic and cellular approaches in lung cancer research.
- Develop and utilize animal models in the analysis of lung cancer
- "Translate" new findings and technologies into innovative clinical applications
- Test the most promising new prevention and treatment strategies in clinical trials

The KLCR Program's Investigator-Initiated Research Initiative continues to provide valuable financial resources to develop novel concepts and identify new avenues of research in lung cancer. These innovative research projects are by nature the most high-risk/high-reward research approaches generating proof-of-concept/proof-of-principle data that will lead to stronger scientific programs, increased publication s and additional extramural funding.

Objectives

1. Recruit existing faculty at the front-lines of cancer research to focus on problems in lung cancer
2. Recruit new faculty both with interests and expertise in cancer that may be applied specifically to lung cancer problems
3. Develop, mentor and focus early stage career investigators and graduate students on lung cancer
4. Continue to support a robust research portfolio for lung cancer at each university
5. Develop intra-programmatic linkages within and between both Cancer Centers
6. Conduct annual scientists' seminars to share research results among lung cancer scientists funded by the KLCR Program

Priorities for 2008-2010

- Recruit additional scientists into the lung cancer research program

- Develop more integrated research programs at each Cancer Center, as well as links between universities
- Utilize KLCR investigator-initiated grants to leverage current and future cancer research into the area of lung cancer

Endpoints 2010

- Publications of lung cancer research at each university continue to break new ground in understanding and intervening in the incidence and mortality from lung cancer
- Research portfolios mature into well-rounded representations of lung cancer study, with progressive increases in extramural funding
- Annual professional meetings for KLCR scientists result in additional collaborative studies
- The Markey Cancer Center and the Brown Cancer Center are identified as increasingly prominent lung cancer research and treatment centers

GOAL 2: Research in Early Detection & Prevention

*"**167.476(5)(a)** Develop an expertise in the area of lung cancer research with an immediate focus on early detection and epidemiology and with an ultimate goal of eradication of lung cancer."*

Despite the direct link between tobacco and lung cancer, only 15% of smokers develop the disease. Thus, a fundamental goal is to discover risk factors that predispose a person to lung cancer. Defining high-risk individuals and development of an effective screening methodology will allow earlier detection, when a malignant tumor is small and asymptomatic, when treatment produces a higher cure rate.

Recent technological advances and new tools for screening have led to renewed trials for detecting early stage lung cancers. Correlative explorations of smoking history, compromised lung function, and biomarkers in serum or exhalate are proposed to help pre-define lung cancer risk in otherwise asymptomatic individuals. Establishment of a biospecimen repository is a key resource to facilitate such studies.

Objectives

1. Conduct screening and early detection research using available and applicable tools in key geographic areas of the state
2. Expand and refine methodologies for risk-factor delineation
3. Validate the use of methodologies for lung cancer screening
4. Identify and develop methodologies for lung cancer prevention
5. Maintain and expand the biospecimen repository for use by lung cancer researchers
6. Capitalize on partnerships with regional and local hospitals and clinics to build an early detection network where research is integral to the relationship
7. Link prevention and early detection studies

Priorities for 2008-2010

- Develop an evidence-based algorithm for lung cancer risk assessment
- Continue the development of biomarker correlates of lung cancer and/or lung cancer risk through advanced molecular surveillance studies
- Through CME programs for Kentucky physicians, articulate current standards of surveillance for lung cancer

Endpoints 2010

- Updated templates for early detection are available in each administrative development district
- The biomarker repositories at the universities are effectively serving advanced early detection investigations
- Further development of candidate molecular markers identified for lung cancer susceptibility and/or early diagnosis
- Further development of lung cancer preventative measures

GOAL 3: Kentucky Clinical Trials Network

*"**167.476(5)(b)** Establish a statewide clinical trial network to make university-based clinical trials available to the community physician in order to bring the most innovative cancer treatments to all Kentuckians in need of these treatments"*

Improvements in the effectiveness of new cancer treatments are accomplished through a series of phased clinical trials: Phase I – identify maximum tolerated doses of new drugs and dose-limiting toxicities; Phase II – test the study drug's effectiveness in specific cancers; Phase III – compare new treatments with established protocols. All of today's recognized cancer treatments were proven by clinical trials before they became generally available. Despite that record of success, most people do not know that cancer clinical trials are the means by which cancer research becomes cancer treatment.

Thousands of cancer clinical trials are underway in the United States. The National Cancer Institute, cooperative groups, academic medical centers, community hospitals, physician practices, and pharmaceutical companies sponsor cancer clinical trials. Of the 1.3 million people who will be diagnosed with cancer this year, only three to five percent will participate in cancer clinical trials.

The University of Kentucky and the University of Louisville have worked together to establish a Clinical Trials Network to educate patients and physicians about the benefits of clinical trials and trial availability, and to assist physicians with planning and implementing trials.

Objectives

1. Increase number of Kentuckians with access to and participating in lung cancer clinical trials.
2. Develop and maintain a critical mass of trained professional staff to support multi-site clinical trials
3. Offer and manage industry-sponsored lung cancer clinical trials through the Network
4. Identify and develop investigator-initiated clinical trials at both universities that can be offered to patients in diverse settings
5. Continually improve the Network's services with input from practicing Kentucky physicians

Priorities for 2008-2010

- Network Office efficiently and effectively processes and manages clinical trials for the Network
- Increase the number of Industry sponsored trials
- Increase the number of therapeutic trials active in the network
- Increase the number of cooperative group trials
- Expansion of investigator-initiated clinical trials from both Institutions.
- Improve training sessions with site investigators and site coordinators
- Increase number of patient accrual to network trials

Endpoints in 2010

- The Kentucky Clinical Trials Network has a continuing stream of novel therapeutic trials available to patients
- The network has an increasing stream of patient accrual
- The Kentucky Clinical Trials Network provides training and information to physicians and citizens throughout the Commonwealth, including updated clinical trial results and new standards of care
- Clinical trials are accessible for all Kentuckians.

GOAL 4: NCI-Designation as Cancer Centers

*"**164.476(5)(c)** Leverage the resources earmarked for the Lung Cancer Research Project toward the certification of the cancer program at the University of Kentucky and the University of Louisville by the National Cancer Institute as a cancer center[.]"*

The Cancer Centers Program of the NCI supports major academic and research institutions throughout the United States to sustain broad based, coordinated, interdisciplinary programs in cancer research. These institutions demonstrate scientific excellence and the ability to integrate a diversity of research approaches to focus on cancer. The NCI and its Cancer Centers Program are dedicated to advancing cancer research to ultimately reduce cancer incidence, morbidity, and mortality.

Designated Cancer Centers receive funds from NCI for scientific infrastructure of the center, including such elements as scientific leadership and administration;

shared/core research resources that give ready access to state-of-the-art technologies; and flexible program development funds that help the center and its associated faculty pursue its planned objectives and take immediate advantage of new research opportunities.

The University of Kentucky and the University of Louisville are each pursuing NCI designation as cancer centers to provide Kentuckians and the nation advanced understandings of and improved interventions in our fight against cancer. Support from the KLCR Program has provided vital financial resources to both institutions during a critical stage of development. The goal of NCI Designation requires a continued investment in scientific expertise, equipment, space and financial resources.

Objectives

1. Expand the base of cancer research expertise, particularly in translational research, with the recruitment of both promising young scientists and established investigators working at the front lines of cancer research.
2. Develop diverse cancer research programs with a high degree of inter- and intra-team collaboration.
3. Provide and promote interactive research opportunities
4. Offer expanded innovative clinical trials, building on combined research underpinnings of the two centers.

Priorities for 2008 -2010

- Continue to expand the overall research bases at each institution, particularly in Translational and Clinical Research
- Increase Extramural Funding with emphasis on funding from the NCI
- Increase NCI Multi-project grants including Program Projects, SPORE Grants and NCI cooperative grants.
- Expansion of research laboratory space
- Develop a more broadly inclusive smoking-related cancer program that involves lung, head & neck, pancreas, cervix and bladder cancers
- Provide all support necessary to process and support submissions for the Markey Cancer Center and James Graham Brown Cancer Center for NCI designation
- Continue to develop multidisciplinary clinics for lung cancer patients.

Endpoints 2010

- Document 3-5 firmly established NCI-designable cancer research programs at each institution, with an emphasis on translational and clinical research.
- Growth of NCI funding at both institutions in the range of $12-$15 million .
- Meet with, receive and respond to recommendations of an External Advisory Committee
- Meet with, receive and respond to recommendations of the NCI Centers Branch Director
- Have a first draft of a P30 application for NCI-designation written.